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EXAMINER	
HELM, CARALYNNE E	

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1615	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/501,247	NEULAND ET AL.	
	Examiner	Art Unit	
	CARALYNNE HELM	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 November 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 5-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 5-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The four factual inquiries of Graham v. John Deere Co. have been fully considered and analyzed in the rejections that follow.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suzuki et al. (previously cited) in view of McGinity et al. (previously cited), Chavannes (previously cited), Goldsworthy et al.(previously cited), and Barth (previously cited).

Suzuki et al. teach an oral pharmaceutical film that includes a water-soluble polymer along with one or multiple medicinal agents and optionally a plasticizer, colorant, and flavoring (see abstract, column 4 lines 8-68, and column 5 lines 6-9 and 24-38). These components are dissolved in a solvent, where water is envisioned, yielding a casting solution (interpreted as aqueous active-ingredient containing drug coating) (see column 5 lines 39-53). The solution is cast via an endless belt type film preparing apparatus or other known methods for preparing a film (see column 5 line 62-column 6 line 8 and column 6 lines 19-22). The solvent is removed by any method customarily adopted in film preparing apparatus and later cut into a desired shape (see column 6 lines 9-17). Suzuki et al. do not explicitly teach additional details of the endless belt type process.

McGinity et al. teach that oral pharmaceutical films were known to contain surface markings such as lettering and numerals for the sake of identification (see paragraphs 1, 51-52, and 59).

Chavannes teaches a method of preparing a solution cast film (see column 2 lines 31-39). The casting process prepares a film with a surface design by passing a carrier, as an endless belt or on a reel, over a roller containing the film-forming solution

on its surface (see column 3 lines 21-34, column 4 lines 31-63; instant claims 5a and 6a). The carrier is envisioned as a metal or paper (see column 3 lines 23-34; instant claim 1e). The carrier, with the applied film, then passes through a drying oven (see figure 7 and column 6 lines 34-38; instant claims 5b and 6b). The film is then stripped (interpreted as peeled) from the carrier by a roller that winds the film onto a reel (see figure 7 and column 6 lines 52-56; instant claims 5c and 6c). The carrier then passes through a buffing brush that cleans the carrier so that it will be ready to begin the coating circuit again (see column 6 lines 57-61).

Goldsworthy et al. teach a process of casting a polymer composite onto the surface of a belt (see column 2 lines 25-28). The material is allowed to cure/dry and is then removed from the belt (see column 2 lines 39-42). Goldsworthy et al. then teach the cleaning of the belt mechanically, with heat (thermal treatment) or solvent before it is returned to the initial portion of the machine for use in the process again (e.g. continuous belt) (see column 2 lines 43-47; instant claims 5di and 6di).). Since applicant has not defined how much residual contaminant corresponds to removal of "essentially all of the contaminants", any amount of cleaning generated by the cleaning processes taught by Goldsworthy et al. are interpreted as removing "essentially all of the contaminants". Although not explicitly taught by Goldsworthy et al, it is commonly known that any cleaning methodology requires the disposal of the waste material removed from the cleaned item. In the case of thermal cleaning, the waste material is, at least in part, in gaseous form.

Barth teaches subjecting sheets of material on a continuous belt to a thermal treatment in a drying oven where the gaseous material removed from the sheets do not

escape to the atmosphere (column 1 lines 57-64). Heated gas is introduced into a chamber through which the sheets travel (interpreted as a thermal treatment) (see figure 1 and column 2 lines 49-53). This treatment liberates material such as solvent and medicine residue which are carried by the gas (see column 3 lines 49-50). This refuse gas is collected by a withdrawal line that is connected to a vacuum pump that removes this gas from the drying chamber to avert its entry into the atmosphere (see column 5 lines 58-67). The vacuum controls the circulation of the air by guiding it out of the drying chamber (controlled air circulation) (see instant claims 5dii and 6dii). Barth goes on to teach that the gas collected by the withdrawal line is fed to an afterburner (see column 3 lines 51-54; instant claims 5dii and 6dii).

It would have been obvious to one of ordinary skill in the art at the time of the invention to use the coating method of Chavannes to prepare the medicinal films of Suzuki et al. due to the suggestion by Suzuki et al. to utilize an endless belt type film preparing apparatus for their film and that of McGinity et al. to include lettering on oral pharmaceutical films to aid in identification. Additionally, it also would have been obvious to modify this method based on the teachings of Goldsworthy et al. who provide mechanical, thermal, and solvent cleaning as functionally equivalent means of cleaning an endless belt utilized in a coating casting method. Therefore the artisan of ordinary skill would also have found it obvious to use thermal treatment to clean the carrier of Suzuki et al. in view of Chavannes and McGinity et al., instead of the taught mechanical means as a simple substitution of one known equivalent element for another to obtain a predictable result. Both Chavannes and the instant specification teach that the carrier employed in this method would become contaminated with material from the coating

solution and these contaminants would include medicinal agent, flavorings, solvent, colorants, and plasticizers (see instant claims 5d-5di and 6d-6di). Since Barth teaches an apparatus that provides a thermal treatment to a continuous belt of sheet material that removes material from its surface, it would also have been to one of ordinary skill in the art at the time of the invention to utilize this apparatus as the source of thermal treatment for the method of Suzuki et al. in view of Chavannes, McGinity et al., and Goldsworthy as a the use of a known technique to improve a similar product in the same way (e.g. removal of undesired components from sheets of product with heat). While the cited references are silent regarding all the mechanisms by which the materials from the cast film contaminate the carrier, they recognize the need to remove residual materials prior to the reuse of the carrier. In addition, all cast components will have a diffusion coefficient in the carrier that will increase as a result of the elevated temperature due to thermal treatment as taught by Goldsworthy et al. A thermal treatment that is sufficient to remove residual materials as taught by Goldsworthy et al. will also remove material that has diffused into the carrier due to the increased rate of diffusion it elicits. Applicants teach that components of the coating will penetrate into the carrier material by diffusion and result in contamination of this carrier when cast onto its surface and later wound onto a reel (see instant specification page 2 lines 4-8 and page 3 lines 1-7). Since the method of Suzuki et al. in view of Chavannes, McGinity et al., Goldsworthy et al., and Barth renders obvious the method steps instantly claimed, their teachings result in a cleaned carrier being reused in a film casting process and also necessarily result in the removal of diffusion contamination from the carrier.

Therefore claims 5 and 6 are obvious over Suzuki et al. in view of Chavannes, McGinity et al., Goldsworthy et al., and Barth.

Claims 1 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suzuki et al. in view of Chavannes, McGinity et al., Goldsworthy et al., and Barth as applied to claims 5 and 6 above, and further in view of Lerdkanchanaporn et al. (previously cited) and Lerdkanchanaporn et al. (previously cited).

Suzuki et al. in view of Chavannes, McGinity et al., Goldsworthy et al., and Barth make obvious the method of method for removing contaminating or undesired substances from a carrier material comprising: a) coating an active-ingredient-containing drug, food or cosmetic coating onto a neutralized carrier material [Applicants teach that neutralization occurs when a carrier is made to be essentially free of contaminants from a coating that was previously applied and removed (see instant specification page 4 lines 16-19). Therefore the cleaned carrier of Suzuki et al. in view of Chavannes, McGinity et al., Goldsworthy, and Barth that is fed back to the coating process is a neutralized carrier], substances within said coating diffusing into and thereby contaminating said carrier material with drug, food or cosmetic contaminating substances, b) drying the coated carrier material to form an active-ingredient-containing or cosmetic film, c) peeling the dried active-ingredient- containing film off the contaminated carrier material and d) subjecting the contaminated carrier material to a thermal treatment which comprises i) passing said contaminated carrier material through a thermal treatment zone at a temperature and during a period of time sufficient to remove essentially all of the drug, food or cosmetic contaminating substances from

the carrier material to form neutralized carrier material, and

ii) feeding the removed contaminants or other undesired substances to a thermal after-burning using controlled air circulation, and e) providing the neutralized carrier material to said coating step. Within the highlighted teachings, this modified reference provides for a paper carrier on a reel (e.g. instant claim 1e), the drying apparatus of Barth forms a tunnel through which the contaminated carrier would travel, therefore qualifying as a drying tunnel (see figure 1; instant claim 7), and the reuse of the carrier in the coating process after it has been cleaned (see instant claim 7). Additionally, since Suzuki et al. teach ibuprofen as a drug envisioned in their film, this modified reference also renders this decontamination method obvious when the coated film contains ibuprofen (see column 4 lines 33-36 and 56). The modified reference does not explicitly teach the temperature at which the cleaning thermal treatment occurs or the time over which the treatment is applied.

Lerdkanchanaporn et al. teach that ibuprofen evaporates at 75ºC -77ºC at atmospheric pressure (see page 71 column 1 paragraph 1).

Lerdkanchanaporn B teaches the coefficient of evaporation per unit area for ibuprofen at a variety of temperatures. A power law fit of this data allows extrapolation of the coefficient of evaporation per area at 77ºC which corresponds to approximately 4.22×10^{-5} mg/cm^{2}s [power law fit of data by examiner yields: (coefficient of evaporation per area) = 10^{-63} x (temperature in Kelvin)$^{23.044}$].

Suzuki et al. in view of Chavannes, McGinity et al., Goldsworthy et al., and Barth clearly envision the contamination of the carrier with material from the film that has been removed. Both one of ordinary skill in the art and the instant inventors would expect that

traces of any of the components in the coating would remain on the carrier as contaminants, and these include the drug. Since Lerdkanchanaporn et al. teach that ibuprofen evaporates at 77ºC, it would have been obvious to one of ordinary skill in the art to apply the taught thermal treatment that cleans the carrier at this temperature to remove residual drug. The temperature 77ºC can be interpreted as "approximately 80 ºC" since applicants have not provided a limiting definition of the term "about" that defines it otherwise. While Suzuki et al. in view of Chavannes, McGinity et al., Goldsworthy et al., Barth, and Lerdkanchanaporn et al. do not explicitly teach the time for the removal of essentially all the undesired substances, the approximate rate of ibuprofen evaporation per area (e.g. coefficient of evaporation) was known based upon the teachings of Lerdkanchanaporn B. One of ordinary skill in the art would have been aware of the dimensions of the carrier and film composition as well as the corresponding amount of carrier contamination. As a result effective variable, it would have been obvious to the artisan of ordinary skill to optimize the thermal treatment cleaning time in light of this data as a matter of routine experimentation. Thus claims 1 and 7 are obvious over Suzuki et al. in view of Chavannes, McGinity et al., Goldsworthy et al., Barth, Lerdkanchanaporn et al. and Lerdkanchanaporn B.

Claims 1 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suzuki et al. in view of McGinity et al., Chavannes, Goldsworthy et al.(previously cited), Dieudonne et al. (previously cited), Wimberger et al. (previously cited), Lerdkanchanaporn et al. and Lerdkanchanaporn B.

Suzuki et al. teach an oral pharmaceutical film that includes a water-soluble polymer along with one or multiple medicinal agents and optionally a plasticizer, colorant, and flavoring (see abstract, column 4 lines 8-68, and column 5 lines 6-9 and 24-38). Ibuprofen is an envisioned medicinal agent (see column 4 lines 33-36 and 56). These components are dissolved in a solvent, where water is envisioned, yielding a casting solution (interpreted as aqueous active-ingredient containing drug coating) (see column 5 lines 39-53). The solution is cast via an endless belt type film preparing apparatus or other known methods for preparing a film (see column 5 line 62-column 6 line 8 and column 6 lines 19-22). The solvent is removed by any method customarily adopted in film preparing apparatus and later cut into a desired shape (see column 6 lines 9-17). Suzuki et al. do not explicitly teach additional details of the endless belt type process.

McGinity et al. teach that oral pharmaceutical films were known to contain surface markings such as lettering and numerals for the sake of identification (see paragraphs 1, 51-52, and 59).

Chavannes teaches a method of preparing a solution cast film (see column 2 lines 31-39). The casting process prepares a film with a surface design by passing a carrier, as an endless belt or on a reel, over a roller containing the film-forming solution on its surface (see column 3 lines 21-34, column 4 lines 31-63; instant claims 1a). The carrier is envisioned as a metal or paper (see column 3 lines 23-34; instant claim 1e). The carrier, with the applied film, then passes through a drying oven (see figure 7 and column 6 lines 34-38; instant claims 1b). The film is then stripped (interpreted as peeled) from the carrier by a roller that winds the film onto a reel (see figure 7 and

column 6 lines 52-56; instant claims 1c). The carrier then passes through a buffing brush that cleans the carrier so that it will be ready to begin the coating circuit again (see column 6 lines 57-61). Applicants teach that components of the coating will penetrate by diffusion into the carrier material resulting in contamination of the carrier when cast onto its surface and later wound onto a reel (see instant specification page 2 lines 4-8 and page 3 lines 1-7). Therefore such contamination must also occur in the process of Chavannes.

Goldsworthy et al. teach a process of casting a polymer composite onto the surface of a belt (see column 2 lines 25-28). The material is allowed to cure/dry and is then removed from the belt (see column 2 lines 39-42). Goldsworthy et al. then teach the cleaning of the belt mechanically, with heat (thermal treatment) or solvent before it is returned to the initial portion of the machine for use in the process again (e.g. continuous belt) (see column 2 lines 43-47; instant claims 1di). Since applicant has not defined how much residual contaminant corresponds to removal of "essentially all of the contaminants", any amount of cleaning generated by the cleaning processes taught by Goldsworthy et al. are interpreted as removing "essentially all of the contaminants". Although not explicitly taught by Goldsworthy et al, it is commonly known that any cleaning methodology requires the disposal of the waste material removed from the cleaned item. In the case of thermal cleaning, the waste material is, at least in part, in gaseous form.

Dieudonne et al. teach an infrared radiator in a continuous oven as a means of applying a thermal treatment to thin plate-like components (see abstract and column 1 lines 4-8)

Wimberger et al. teach a process where a paper web (carrier) is passed through a thermal treatment zone such that a surface contaminant (solvent) is removed via a thermal treatment and fed to an afterburner via a fan (controlled air circulation) (see column 1 lines 50-59, column 2 lines 66-68; instant claims 1 and 3).

Lerdkanchanaporn et al. teach that ibuprofen evaporates at 75ºC -77ºC at atmospheric pressure (see page 71 column 1 paragraph 1).

Lerdkanchanaporn B teaches the coefficient of evaporation per unit area for ibuprofen a variety of temperatures. A power law fit of this data allows extrapolation of the coefficient of evaporation per area at 77ºC which corresponds to approximately $4.22x10^{-5}$ mg/cm^{2}s [power law fit of data by examiner yields: (coefficient of evaporation per area) = 10^{-63} x (temperature in Kelvin)$^{23.044}$].

It would have been obvious to one of ordinary skill in the art at the time of the invention to use the coating method of Chavannes to prepare the medicinal films of Suzuki et al. due to the suggestion by Suzuki et al. to utilize an endless belt type film preparing apparatus for their film and that of McGinity et al. to include lettering on oral pharmaceutical films to aid in identification. Additionally, it also would have been obvious to modify this method based on the teachings of Goldsworthy et al. who provide mechanical, thermal, and solvent cleaning as functionally equivalent means of cleaning an endless belt utilized in a coating casting method. Therefore the artisan of ordinary skill would also have found it obvious to use thermal treatment to clean the carrier of Suzuki et al. in view of Chavannes and McGinity et al., instead of taught mechanical means as a simple substitution of one known equivalent element for another to obtain a predictable result. Both Chavannes and the instant specification teach that the carrier

employed in this method would become contaminated with material form the coating solution and these contaminants would include medicinal agent, flavorings, solvent, colorants, and plasticizers (see instant claims 1d-1di). Since Dieudonne et al. teaches an apparatus that provides a thermal treatment to a continuous belt of plate-like material, it would also have been one of ordinary skill in the art at the time of the invention to utilize this apparatus as the source of thermal treatment for the method of Suzuki et al. in view of Chavannes, McGinity et al., and Goldsworthy as a simple substitution of one known equivalent element for another (e.g. general thermal treatment device for infrared thermal treatment device). This thermal cleaning treatment would necessarily liberate gaseous waste, therefore it also would have been obvious to feed this material to an afterburner as taught by Wimberger et al. as the application of a known technique to a similar method ready for improvement to yield a predictable result.

Suzuki et al. in view of Chavannes, McGinity et al., Goldsworthy et al., Dieudonne et al., and Wimberger et al. clearly envision the contamination of the carrier with material from the film that has been removed as well as ibuprofen as a component of the film. Both one of ordinary skill in the art and the instant inventors would expect that traces of any of the components in the coating would remain on the carrier as contaminants, and these include the drug. Since Lerdkanchanaporn et al. teach that ibuprofen evaporates at 77ºC, it would have been obvious to one of ordinary skill in the art to apply the taught thermal treatment that cleans the carrier at this temperature to remove residual drug. The temperature 77ºC can be interpreted as "approximately 80 ºC" since applicants have not provided a limiting definition of the term "about" that defines it otherwise. Suzuki et al. in view of Chavannes, McGinity et al., Goldsworthy et

al., Dieudonne et al., and Wimberger et al. do not explicitly teach the time for the removal of essentially all of the undesired substances, the approximate rate of ibuprofen evaporation per area (coefficient of evaporation) was known based upon the teachings of Lerdkanchanaporn B. One of ordinary skill in the art would have been aware of the dimensions of the carrier and film composition as well as the corresponding amount of carrier contamination. As a result effective variable, it would have been obvious to the artisan of ordinary skill to optimize the thermal treatment cleaning time in light of this data as a matter of routine experimentation. While the cited references are silent regarding all the mechanisms by which the materials from the cast film contaminate the carrier, they recognize the need to remove residual materials prior to the reuse of the carrier. In addition, all cast components will have a diffusion coefficient in the carrier that will increase as a result of the elevated temperature due to thermal treatment as taught by Goldsworthy et al. A thermal treatment that is sufficient to remove residual materials as taught by Goldsworthy et al. will also remove material that has diffused into the carrier due to the increased rate of diffusion it elicits. Applicants teach that components of the coating will penetrate into the carrier material by diffusion and result in contamination of this carrier when cast onto its surface and later wound onto a reel (see instant specification page 2 lines 4-8 and page 3 lines 1-7). Since the method of Suzuki et al. in view of Chavannes, McGinity et al., Goldsworthy et al., Dieudonne et al., and Wimberger et al. renders obvious the method steps instantly claimed, their teachings result in a cleaned carrier being reused in a film casting process and also necessarily result in the removal of diffusion contamination from the carrier. Thus claims 1 and 8 are

obvious over Suzuki et al. in view of Chavannes, McGinity et al., Goldsworthy et al., Dieudonne et al., Wimberger et al., Lerdkanchanaporn et al. and Lerdkanchanaporn B.

Response to Arguments

Applicants' arguments submitted November 5, 2010, have been fully considered but are not persuasive regarding the rejection made under 35 USC 103(a). Applicants' arguments regarding the rejection made under 35 USC 112, first paragraph are persuasive; therefore the rejection is hereby withdrawn.

Regarding the rejections made under 35 USC 103(a):

Applicants argue that the cited references do not recognize the removal of contaminants that have diffused into a carrier as an issue. Prior art clearly details the recognition of the need to clean residual components from coating materials cast onto the surface of carrier webs prior to their reuse as carriers (see Goldsworthy et al. column 2 lines 43-47 and Chavannes column 6 lines 57-61). Regardless of the mechanism responsible for locating the contaminants in or on the carrier, the detriment posed by residual coating materials to inter-batch consistency was known and recognized at the time of the invention. Since thermal treatment was a known methodology for removing residual materials from carrier webs, there was motivation for the artisan of ordinary skill to apply such a method to clean a carrier web prior to its reuse in a coating process line. A thermal treatment that is sufficient to remove material from a carrier in general will also remove material that has diffused into its surface by virtue of the increased diffusion coefficient of the material and the resulting increase in

its rate of diffusion. Moreover the occurrence of diffusion in a film casting process line is not an unexpected result. Diffusion is a well known thermodynamic phenomenon that generally occurs due to a concentration gradient and a film casting process by its very nature creates a concentration gradient between the casting coating and the carrier web which is initially devoid of ingredients from the coating.

Applicants go on to argue that one of the set of references does not teach the removal of diffused contaminants. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In addition, applicants provide a quotation on page 10 or the remarks that is attributed to Chavannes discussing the coating of their web "so it is not attacked by components within the coating." Chavannes teaches protecting the coating web from attack by solvents or diluents, not just any component in the material cast onto the web as applicants suggest (see column 3 lines 34-37). In spite of this protective layer, the cast material still contaminates the web such that it needs to be cleaned prior to its reuse (see column 6 lines 57-61). In fact, applicants themselves envision silicone coated paper as carrier materials which would also have this solvent resistance. Thus the presence of such a coating on a carrier does not stop the diffusion of contaminants into the carrier, contrary to applicants' suggestion. Applicants further provide arguments against a subset of the references cited which is insufficient to rebut the rejection based upon a larger set of references.

Applicants note the teaching of Suzuki et al. of casting on an endless belt multiple times while neglecting the teachings of Chavannes who teach that such belts

were known to be made of paper or metals when used for casting films. Similarly, applicants note the teaching of McGinity et al. to clean their belt by mechanical means but do not address the fact that Goldsworthy et al. teach that post-casting cleaning of belts can be accomplished by mechanical, thermal, or solvent cleaning. Thus the teachings that applicants argue are absent in one cited reference are invariably provided by another cited reference.

Applicants also argue that the teachings of Goldsworthy point to the removal of only surface debris and the application of a coating to protect the carrier from contamination, from the cast material. No evidence has been provided to demonstrate that the cleaning procedures taught by Goldsworthy only removes debris on the surface. In addition, given that Goldsworthy explicitly teach cleaning procedures for the casting carrier prior to its reuse, clearly they recognized that the protective coating highlighted by applicants would not be sufficient to protect the carrier from contamination by the cast material. Applicants also argue that the interpretation of "essentially all contaminants" in the rejection is conclusory. The specification does not define the quantity of contaminant that constitutes "essentially all". Since the purpose of the removal of residue casting material left behind after the removal of the cast coating is to have consistency between cast batches, one of ordinary skill in the art would have wanted to remove as much residue as possible. Any amount of removal would improve inter-batch consistency and this quantity can be reasonably interpreted as "essentially all" since applicants have not defined it otherwise.

In response to applicant's argument that Suzuki et al., Chavannes, McGinity et al., Goldsworthy et al. and Barth are nonanalogous art, it has been held that a prior art

reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Suzuki et al. teach the preparation of oral pharmaceutical film via an endless belt, McGinity et al. teach oral pharmaceutical films while Chavannes teaches the casting of a film onto an endless belt. Goldsworthy et al. teach of the residual materials left when an endless belt is used as the carrier for cast material as well as thermal treatment to remove them and Barth teaches the disposal of material removed from a continuous belt subjected to thermal treatment. Therefore these references are in fact analogous to one another and can be combined.

In contrast to applicants' suggestion, the teachings of Lerkanchanaporn et al. and Lerkanchanaporn B coupled with those of Suzuki et al., Chavannes, McGinity et al., Goldsworthy et al. and Barth provides for both a temperature and time for a thermal treatment to a paper carrier in order to clean it in preparation for its return to the beginning of and film casting process line.

Applicants repeatedly argue that each of the cited references did not teach the invention in its entirety on its own as well as aspects in each reference that were unrelated to the instantly claimed invention. The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the

references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CARALYNNE HELM whose telephone number is (571)270-3506. The examiner can normally be reached on Monday through Friday 9-5 (EDT).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on 571-272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Caralynne Helm/
Examiner, Art Unit 1615

/Juliet C Switzer/
Primary Examiner, Art Unit 1634